UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,627	04/28/2006	Derek Nigel John Hart	DAVI257.004APC	9936

20995 7590 05/20/2008

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,627	HART ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 4, 16 and 36, drawn to CD4+ CMRF-35++ CD45RO+ T-cells.

Group II, claim(s) 5 and 17, drawn to CD4+ CMRF-35+ CD45RO+ T-cells.

Group III, claim(s) 6 and 18, drawn to CD4+ CMRF-35- CD45RO+ T-cells.

Group IV, claim(s) 7 and 19, drawn to CD4+ CMRF-35+ CD45RO- T-cells.

Group V, claim(s) 8 and 20, drawn to CD4+ CMRF-35- CD45RO- T-cells.

Group VI, claim(s) 24 and 37, drawn to a method for assessing the immunological potential of a subject said method comprising obtaining a sample from said subject comprising T-cells and subjecting the sample to cell surface discrimination means to determine the presence, absence or level of CD4+ CMRF-35++ CD45RO+ CXCR3+ T-cells.

Group VII, claim(s) 25, drawn to a method for assessing the immunological potential of a subject said method comprising obtaining a sample from said subject comprising T-cells and subjecting the sample to cell surface discrimination means to determine the presence, absence or level of CD4+ CMRF-35+ CD45RO+ T-cells.

Group VIII, claim(s) 26, drawn to a method for assessing the immunological potential of a subject said method comprising obtaining a sample from said subject comprising T-cells and subjecting the sample to cell surface discrimination means to determine the presence, absence or level of CD4+ CMRF-35- CD45RO+ T-cells.

Group IX, claim(s) 27, drawn to a method for assessing the immunological potential of a subject said method comprising obtaining a sample from said subject comprising T-cells and subjecting the sample to cell surface discrimination means to determine the presence, absence or level of drawn to CD4+ CMRF-35+ CD45RO- T-cells.

Group X, claim(s) 28, drawn to a method for assessing the immunological potential of a subject said method comprising obtaining a sample from said subject comprising

T-cells and subjecting the sample to cell surface discrimination means to determine the presence, absence or level of CD4+ CMRF-35- CD45RO- T-cells.

Group XI, claim(s) 34 and 35, drawn to a computer program product and a computer making use of said computer program product for assessing the presence or absence or level of a sub-population of CD4+ T-cells said product comprising: (i) code that receives, as input values, the identity of a reporter molecule associated with a labeled antibody which recognizes one of a CMRF-35 epitope or CD45RO marker; (ii) code that compares said input values with reference values to determine the level of CMRF-35 epitope or CD45RO; and (iii) a computer readable medium that stores the codes.

2. Claims 1-3 and 9-15 link(s) the inventions of Groups I-V. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-3 and 9-15.

   Claims 21-23 and 29-33 link(s) the inventions of Groups VI-X. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 21-23 and 29-33.

   Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

   Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups III and V, for example, lack a special technical feature in view of the teachings of Robichaud et al. (J Biol Chem. 2002 Jun 28;277(26):23733-41) as evidenced by the instant specification at page 94, 3rd paragraph. In particular, Robichaud teaches Jurkat T cell lines which are CD4+ and CD45RO+ or CD45RO-

(see, in particular, page 23734, right column, 2nd paragraph), and as evidenced by the instant specification at page 94, 3rd paragraph, Jurkat T cells are CMRF-35-.

Election of Species Requirement

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. If applicant elects any one of Groups I-V, applicant is required to further elect a species of subject from which the isolated CD4+ T cells are derived selected from among the particular species of subjects recited in claims 9-13 and 15 OR from "normal subjects" as disclosed in the instant application for example at pages 88-89 Examples 2 and 3.

6. If applicant elects any one of Groups VI-X, applicant is required to further elect a species of subject whose immunological potential will be assessed on the basis of the expression of CD4, CMRF-35 and CD45RO selected from among the particular species of subjects recited in claims 30, 32 and 33 OR from "normal subjects" as disclosed in the instant application for example at pages 88-89 Examples 2 and 3.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

   Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the cell lines of Robichaud were derived from a subject having a T cell cancer.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
May 13, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644